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Filed : **February 10, 2004**

REMARKS

The claims have been amended as set forth above. Claim 22 has been cancelled without prejudice toward future prosecution. Claims 1-21 and 23-25 have been amended as set forth above. The specific changes to the claims are shown with added text underlined and with ~~deleted text in strikethrough~~.

Claim 1 has been amended to recite "[a]n expression vector," which is supported, for example, by the title of the application. Claim 1 also has been amended to recite that the reading frame does not encode a whole tumor associated antigen. Support for that amendment is found in the specification as filed, for example, in paragraph [0011], which states "wherein the whole antigen is not encoded." Finally, Claim 1 has been amended to recite that the "expression vector comprises a promoter operably linked to said reading frame." Exemplary support for the amendment is found in original Claim 22, which has been cancelled.

Also, Claims 2-21 and 24 have been amended to correct the antecedent basis in view of the amendment to Claim 1 to recite "expression vector." Claims 11-16 and 18 further have been broadened to recite "comprising" rather than "consisting essentially of." Claim 19 has been amended as set forth above. Support for the amendment is found, for example, in paragraphs [0054], [0056] and [0068]. Claim 23 has been amended to correct the claim dependency in view of the cancellation of Claim 22.

Also, new Claims 26-31 are added. Exemplary support for new Claim 26 is found in original Claims 11-17. Exemplary support for new Claim 27 is found paragraph [0119]. Furthermore, support for new Claims 28 and 29 is found, for example, in the original claims as filed and in paragraphs [0028], [0029] and [0070].

No new matter has been added by the amendments or by the addition of the new claims. Thus, Claims 1-21 and 23-31 are pending and presented for examination.

Discussion of Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected Claims 11-16 and 18 as being ambiguous and unclear in the recitation of "consists essentially of." As set forth above, those claims have been amended to recite "comprising" rather than "consists essentially of." Therefore, the rejection is moot.

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The Examiner also rejected Claim 19 as being ambiguous and unclear in the recitation of "essentially a housekeeping epitope." As set forth above, the word "essentially" has been deleted from Claim 19. Therefore, the rejection is moot.

Discussion of Rejections Under 35 U.S.C. § 102

The Examiner rejected Claims 1-19 and 21 under 35 U.S.C. § 102 as being anticipated by Clark et al. (Nature Genetics, 7(4):502-508 (1994)) and Crew et al. (The EMBO Journal, 14(10):2333-2340 (1995)). Applicants respectfully disagree that the amended and new claims are anticipated by Clark et al. or Crew et al.

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986).

Clark et al. Does Not Anticipate:

The Examiner rejected Claims 1-19 and 21 under 35 U.S.C § 102(b) as being anticipated by Clark et al. (Nature Genetics, 7(4):502-508 (1994)). The Examiner argued that Claim 1 "is drawn to a reading frame 'comprising' a fragment," and that accordingly, the reading frame reads upon the full length SSX-2 nucleic acid comprising the fragment.

Clark et al. does not anticipate Claim 1 because the claim has been amended to recite that the reading frame "does not encode a whole tumor associated antigen." Clark et al. discloses a naturally occurring, full-length gene that encodes a whole tumor antigen associated with human synovial sarcoma. The gene is a naturally occurring chimeric gene resulting from a translocation involving the SYT and SSX genes. Also, Clark et al. does not anticipate because, consistent with the statements by the Examiner in the Office Action, it fails to disclose an "expression vector [that] comprises a promoter operably linked to said reading frame." Therefore, Claim 1 as amended is not anticipated by Clark et al.

The Examiner further argues that Clark et al. anticipates on Claims 2-8, 12-16, 18 and 19. Applicants disagree. As discussed above, Clark et al. does not anticipate Claim 1, and therefore, it does not anticipate the claims depending therefrom. Additionally, Applicants note that Clark et al. only discloses a sequence that encodes amino acids corresponding to positions 111-188 of

SSX-2. Therefore, Clark et al. cannot anticipate any of Claims 11-18 or new Claim 26, because Clark et al. does not disclose a sequence encoding the specified amino acids. Similarly, Clark does not anticipate any of claims 9-10 as it does not disclose a fragment of SSX-2 that is less that 10-25% the length of that antigen. Thus, Clark et al. does not anticipate amended Claim 1 or any of the Claims depending therefrom.

Clark et al. does not anticipate new independent Claims 27 and 28 because Clark et al. fails to disclose an isolated nucleic acid comprising a reading frame that does not encode the complete SSX-2 antigen and comprising a liberation sequence. The term liberation sequence is clearly defined in the specification in paragraph [0070]. Clark et al. does not disclose such a designed or engineered sequence alone, much less in combination with the recited reading frame.

Also, Claim 28 is not anticipated because Clark et al. does not disclose an isolated nucleic acid sequence encoding both a fragment of tumor-associated antigen SSX-2 and a liberation sequence.

Crew et al. Does Not Anticipate:

The Examiner rejected Claims 1-19 under 35 U.S.C § 102(b) as being anticipated by Crew et al. (The EMBO Journal, 14(10):2333-2340 (1995)). The Examiner argues that Crew et al. teaches a nucleic acid encoding the SSX-1 polypeptide, which has some amino acid sequence that is identical to SSX-2. The Examiner also argues that Crew et al. anticipates because the claims were drafted in open format, such that the sequences encoding SSX-2 and SSX-1, disclosed in Crew et al. read on Claim 1.

Similar to Clark et al., Crew et al. discloses a full-length, naturally occurring chimeric gene resulting from a translocation of the SYT and SSX genes (SSX-1 and SSX-2), which chimeric gene encodes a tumor antigen associated with human synovial sarcoma. Crew et al. also discloses the complete sequences for tumor associated antigens, SSX-1 and SSX-2.

However, Crew et al. does not anticipate because it only discloses a sequence that encodes "a whole tumor associated antigen." Crew et al. provides no disclosure of an expression vector comprising a reading frame encoding less than a whole antigen. Also, Crew et al. does not anticipate because, consistent with the statements by the Examiner in the Office Action, it fails to

disclose an "expression vector [that] comprises a promoter operably linked to said reading frame." Therefore, Crew et al. does not anticipate amended Claim 1.

Crew et al. does not anticipate new independent Claim 27 because Crew et al. fails to disclose an isolated nucleic acid comprising both a reading frame that does not encode the complete SSX-2 antigen and a liberation sequence. Also, Claim 28 is not anticipated because Clark et al. does not disclose an isolated nucleic acid sequence encoding both a fragment of tumor associated antigen SSX-2 and a liberation sequence.

For at least the reasons discussed above, Clark et al. and Crew et al. do not anticipate any of the claims. Therefore, Applicants respectfully request reconsideration and withdrawal of the instant rejections under § 102.

Discussion of Rejections Under 35 U.S.C. § 103

The Examiner rejected Claims 1-8, 12-16 and 18-25 under 35 U.S.C. § 103(a) as being unpatentable over Clark et al. in view of Campbell (Monoclonal Antibody Technology [1985], pages 1-32). The Examiner also rejected Claims 1-25 over Clark et al. in view of Campbell. Applicants respectfully disagree.

To establish a *prima facie* case of obviousness all of the claim limitations must be taught or suggested by the prior art. *See In re Royka*, 490 F.2d 981 (CCPA 1974) and M.P.E.P. § 2143.03.

Applicants submit that Claim 1 and new independent Claims 27 and 28 are not obvious over the cited references alone or when combined, because the references do not teach or suggest each and every claim limitation. The deficiencies of Clark et al. and Crew et al. as applied to Claims 1, 27 and 28 are discussed above. Campbell does not disclose the missing features of those claims. Therefore, amended Claim 1 and new independent Claims 27 and 28 cannot be obvious over the cited references.

Thus, Applicants respectfully request reconsideration and withdrawal of the instant obviousness rejection.

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Conclusion

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action have been addressed and that the application is in condition for allowance. Accordingly, Applicant requests the expeditious allowance of the pending claims.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned to discuss such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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